CLAIMS

We claim:

1. A method of treating a human patient with a condition of lipoatrophy, which comprises administering to the patient an effective dose of leptin, leptin analog or leptin derivative.

2. The method of claim 1, wherein said leptin, leptin analog or leptin derivative is administered together with a pharmaceutically acceptable carrier.

3. The method of claim 1, wherein said leptin, leptin analog or leptin derivative is administered in a pharmaceutically acceptable diluent.

4. The method of claim 1, wherein the patient has a leptin level of 4 ng/ml or less before administration of leptin, leptin analog, or leptin derivative.

5. The method of claim 4, wherein the patient has a leptin level of 2 ng/ml or less before administration of leptin, leptin analog, or leptin derivative.

6. The method of claim 1, wherein the patient has an acquired form of lipoatrophy.

7. The method of claim 6, wherein the patient is HIV positive.

8. The method of claim 7, wherein the acquired form of lipoatrophy is related to treating the HIV positive patient with highly active antiretroviral therapy (HAART).

9. The method of claim 1, wherein the patient has a genetic form of lipoatrophy.

10. The method of claim 9, wherein the genetic form of lipoatrophy is congenital generalized lipoatrophy.

11. The method of claim 1, wherein the condition of lipoatrophy comprises metabolic abnormalities.

12. The method of claim 11, wherein the metabolic abnormalities are selected from a group consisting of hyperglycemia, dyslipidemia, hyperlipidemia, hypercholesterolemia, hypertriglyceridemia, atherosclerosis, vascular restenosis, and insulin resistance.

13. The method of claim 11, wherein the metabolic abnormalities comprise diabetes.

14. The method of claim 11, wherein the metabolic abnormalities comprise insulin resistance.

15. The method of claim 11, wherein the metabolic abnormalities comprise hypertriglyceridemia.

16. The method of claim 1, wherein the condition of lipoatrophy comprises hepatomegaly.

17. The method of claim 1, wherein the condition of lipoatrophy comprises an abnormality in the distribution of fat tissue.

18. The method of claim 1, wherein said leptin, leptin analog, or leptin derivative is administered subcutaneously.

19. The method of claim 18, wherein the leptin is selected from the group consisting of recombinant human leptin of SEQ ID NO: 1 and SEQ ID NO: 2.

20. The method of claim 19, wherein said leptin is administered together with a pharmaceutically acceptable carrier.

21. The method of claim 19, wherein said leptin is administered in a pharmaceutically acceptable diluent.

22. The method of claim 1, wherein said leptin, leptin analog, or leptin derivative is delivered to the patient using a vector comprising nucleic acid sequences encoding for leptin, leptin analog, or leptin derivative, respectively.

23. The method of claim 1, wherein said leptin is recombinant human leptin.

24. The method of claim 23, wherein said recombinant human leptin is SEQ ID NO: 1.

25. A method of determining a predisposition of a lipoatrophic patient to respond to treatment with leptin, leptin analog, or leptin derivative, the method comprising:

(a) determining a leptin level in the patient prior to said treatment; and

(b) ascertaining whether the leptin level is less than or equal to approximately 4 ng/ml.

26. The method of claim 25, wherein said patient is a male and said leptin level is less than or equal to approximately 2 ng/ml prior to treatment.

27. The method of claim 25, wherein said patient is a female.

28. A method of determining a predisposition of a lipoatrophic patient to respond to treatment with leptin, leptin analog, or leptin derivative, the method comprising:

(a) determining a leptin level in the patient prior to said treatment; and

(b) ascertaining whether the leptin level of (i) a male patient is less than or equal to approximately 2 ng/ml, or (ii) a female patient is less than or equal to approximately 4 ng/ml.

29. A method for treating lipoatrophy, comprising a pharmaceutical regimen comprising a combination of protease inhibitor and leptin, leptin analog, or leptin derivative.

30. A method for treating lipoatrophy, comprising a pharmaceutical regimen comprising a combination of leptin, leptin analog, or leptin derivative and at least one compound selected from the group consisting of thiazolidinediones, fibrates, statins and metformin.

31. A method of treating a human with metabolic abnormalities associated with lipoatrophy, comprising administering leptin, leptin analog, or leptin derivative.

32. An improved kit for determining the predisposition of a human patient with lipoatrophy to respond to treatment with leptin, leptin analog or leptin derivative, the improvement comprising means for determining whether the leptin level of the patient prior to said leptin treatment is:

(i) less than or equal to approximately 2 ng/ml if said patient is male, or

(ii) less than or equal to approximately 4 ng/ml if said patient is female.